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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. CIPLA USA, INC., and CIPLA LIMITED, Defendants.	Case No.: 1:24-cv-10213 **COMPLAINT** *Document Filed Electronically*

Plaintiffs Salix Pharmaceuticals, Inc.; Salix Pharmaceuticals, Ltd.; Alfasigma, S.p.A.; and Bausch Health Ireland, Ltd. (collectively, "Salix"), by their attorneys, Morgan, Lewis & Bockius

LLP, file this Complaint for patent infringement against Cipla USA, Inc. ("Cipla USA"), and Cipla Limited (collectively "Cipla" or "Defendants") and hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Xifaxan® (rifaximin tablets, 550 mg) prior to the expiration of U.S. Patent Nos. 11,564,912 (the "'912 patent"), 11,779,571 (the "'571 patent") and U.S. Patent No. 8,193,196 (the "'196 patent") (collectively, the "Xifaxan® patents" or "patents-in-suit").

2. By letter dated September 18, 2024 ("Notice Letter"), Defendants notified Salix that they had submitted to FDA ANDA No. 219570 ("Cipla ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, and/or sale of generic rifaximin 550 mg tablets ("Cipla's ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Xifaxan® patents. The Notice Letter stated that Defendants have received a Paragraph IV acceptance acknowledgement receipt letter from FDA.

PARTIES

3. Plaintiff Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

4. Plaintiff Salix Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

5. Plaintiff Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having a principal place of business at Via Ragazzi del '99, 5, 40133 Bologna, Italy.

6. Plaintiff Bausch Health Ireland Ltd. is a company organized and existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland.

7. On information and belief, defendant Cipla USA is a corporation organized and existing under the laws of Delaware with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. On information and belief, Cipla Limited is a company organized and existing under the laws of the Republic of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India. On information and belief, Cipla Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Cipla USA.

9. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Limited.

10. On information and belief, Cipla USA and Cipla Limited acted in concert to prepare the Cipla ANDA. On information and belief, both Cipla USA and Cipla Limited assisted with the preparation of the Cipla ANDA.

11. On information and belief, Cipla USA and Cipla Limited acted in concert to submit the Cipla ANDA to FDA. On information and belief, Cipla Limited directed Cipla USA to submit the Cipla ANDA from Cipla USA's principal place of business in New Jersey.

12. On information and belief, if the Cipla ANDA were approved, Cipla USA and Cipla Limited would directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. On information and belief, Cipla USA and Cipla Limited are agents of each other, and/or operate in concert as integrated parts of the same business group, including regarding the ANDA Product, and enter into intercompany agreements with each other. On information and belief, Cipla USA and Cipla Limited participated in, assisted, and cooperated with each other in the acts complained of herein.

13. On information and belief, following any FDA approval of the Cipla ANDA, Cipla USA and Cipla Limited will act in concert to distribute and sell the ANDA Product throughout the United States, including within New Jersey.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

15. Cipla USA is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Cipla USA is qualified to do business in New Jersey and has its principal place of business in New Jersey. On information and

belief, Cipla USA develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey and therefore transacts business within New Jersey related to Salix's claims, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

16. On information and belief, the Court has personal jurisdiction over Cipla USA because Cipla USA regularly engages in patent litigation concerning FDA approved branded drug products in this District and purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Cubist Pharmaceuticals. LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

17. Cipla Limited is subject to personal jurisdiction in New Jersey because, among other things, Cipla Limited itself, and through its wholly owned subsidiary Cipla USA, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla Limited itself, and through its wholly owned subsidiary Cipla USA, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within the New Jersey, and/or has engaged in systematic and continuous business contacts within the New Jersey. In addition, Cipla Limited is subject to

personal jurisdiction in New Jersey because, on information and belief, it controls Cipla USA, and therefore Cipla USA's activities in this jurisdiction are attributed to Cipla Limited.

18. On information and belief, Cipla Limited consented to jurisdiction, did not contest jurisdiction, and asserted claims and/or counterclaims in New Jersey in one or more prior litigations, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla Ltd.*, No. 2:20-cv-14890 (D.N.J. Oct. 27, 2020) (ECF. 8); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J. Aug. 26, 2019) (ECF. 11); *Cubist Pharmaceuticals LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

19. In the alternative, this Court has personal jurisdiction over Cipla Limited under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Salix's claims arise under federal law; (b) Cipla Limited is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Cipla Limited has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla Limited satisfies due process, and is consistent with the Constitution and laws of the United States.

20. On information and belief, if the Cipla ANDA were approved, Defendants would directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Defendants' practices for the marketing

and distribution of other generic pharmaceutical products. On information and belief, Defendants regularly do business in New Jersey, and they have placed other generic pharmaceutical products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the patents-in-suit in the event that the ANDA Product is approved before the patents-in-suit expire.

21. Pursuant to 28 U.S.C. §§ 1391 and 1400(b), venue is proper in this District as to Cipla USA because, amongst other things, on information and belief, Cipla USA (a) has its principal place of business in New Jersey and is subject to personal jurisdiction in this District; (b) has acted in concert with Cipla Limited to seek approval from FDA to market and sell the ANDA Product in this District; (c) prepared and submitted the Cipla ANDA from its principal place of business in New Jersey; (d) conducts business, alone and/or in concert with Cipla Limited, from its place of business located in this District; (e) has engaged in regular and established business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities concerning the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (f) will directly benefit from the approval of the Cipla ANDA.

22. On information and belief, Cipla USA is in the business of preparing and submitting ANDAs on behalf of its related entities, including Cipla Limited, from its principal place of business in New Jersey.

23. On information and belief, Cipla USA is regularly compensated for its services of preparing and submitting ANDAs on behalf of its related entities, including Cipla Limited.

24. On information and belief, Cipla Limited consented to Cipla USA acting on its behalf when it engaged Cipla USA to prepare and submit the Cipla ANDA on Cipla Limited's behalf.

25. On information and belief, Cipla USA acted and continues to act on Cipla Limited's behalf. On information and belief, Cipla Limited owns the Cipla ANDA and thus controlled and directed Cipla USA's acts related to the preparation and submittal of the Cipla ANDA.

26. On information and belief, Cipla USA is Cipla Limited's agent regarding the Cipla ANDA, and in that capacity, Cipla USA prepared and submitted the Cipla ANDA on Cipla Limited's behalf from its principal place of business in New Jersey.

27. On information and belief, Cipla USA consented to venue, did not contest venue, and asserted claims and/or counterclaims in New Jersey in one or more prior litigations, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Cubist Pharmaceuticals. LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

28. Pursuant to 28 U.S.C. §§ 1391 and 1400(b), venue is proper in this district as to Cipla Limited because, amongst other things, Cipla Limited is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

29. Cipla Limited owns the Cipla ANDA and will directly benefit from the approval of Cipla's ANDA.

30. On information and belief, Cipla USA is Cipla Limited's agent, and in that capacity, Cipla USA prepared and submitted the Cipla ANDA on Cipla Limited's behalf from its principal place of business in New Jersey.

31. On information and belief, Cipla Limited consented to Cipla USA acting on its behalf when it engaged Cipla USA to prepare and submit the Cipla ANDA on Cipla Limited's behalf.

32. On information and belief, Cipla USA consented to act on behalf of Cipla Limited when it submitted the Cipla ANDA.

33. On information and belief, Cipla Limited controlled and directed Cipla USA's acts related to the preparation and submittal of the Cipla ANDA.

34. On information and belief, by virtue of its agency relationship with Cipla USA, Cipla Limited has a regular and established place of business in New Jersey.

35. On information and belief, Cipla Limited consented to venue, did not contest venue, and asserted claims and/or counterclaims in New Jersey in one or more prior litigations, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla Ltd*., No. 2:20-cv-14890 (D.N.J. Oct. 27, 2020) (ECF. 8); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc*., No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc.,*

et al. v. Cipla Ltd. & Cipla USA, Inc., No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J. Aug. 26, 2019) (ECF. 11); *Cubist Pharmaceuticals LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

THE XIFAXAN® NDA

36. Salix Pharmaceuticals, Inc. holds the approved New Drug Application ("NDA") Nos. 021361 and 022554 (a supplement to NDA No. 021361 that was granted a new NDA number for Xifaxan® (rifaximin) 550 mg tablets).

37. FDA approved NDA No. 021361 for Xifaxan® 200 mg tablets on May 25, 2004 and approved NDA No. 022554 for Xifaxan® 550 mg tablets on March 24, 2010. Xifaxan® 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy recurrence in adults and the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults.

THE PATENTS-IN-SUIT

38. On October 10, 2023, the '571 patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '571 patent is attached hereto as Exhibit A.

39. On January 31, 2023, the '912 patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '912 patent is attached hereto as Exhibit B.

40. On June 5, 2012, the '196 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wassermann, S.p.A. as assignee. AlfaSigma, S.p.A. is the successor to Alfa

Wasserman, S.p.A. by operation of law. A true and correct copy of the '196 patent is attached hereto as Exhibit C.

41. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '571 patent, the '912 patent, and the '196 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan®.

42. Pursuant to agreements entered into between Bausch Health Ireland Ltd., Salix Pharmaceuticals, Inc., and Alfasigma S.p.A., Bausch Health Ireland Ltd. and Salix Pharmaceuticals, Inc. have substantial rights in the '196 patent, including, but not limited to, an exclusive license to those patents in the United States and the right to sue for infringement of those patents in the United States. Pursuant to those agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

43. On information and belief, Defendants submitted the Cipla ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Cipla's ANDA Product as a generic version of Xifaxan® 550 mg tablets.

44. On information and belief, the Cipla ANDA seeks FDA approval of Cipla's ANDA Product for the indication of the treatment of IBS-D in adults.

45. The Notice Letter stated that the Cipla ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding several Xifaxan® patents, including the '571 patent, the '912 patent, and the '196 patent, and that, in Defendants' opinion, certain claims of the Xifaxan® patents are invalid, unenforceable, and/or not infringed.

46. The Notice Letter does not allege non-infringement of the claims of the ’571 patent and the ’912 patent.

47. By not identifying non-infringement defenses for the claims of the ’571 patent and ’912 patent in the Notice Letter, Defendants admit the ANDA Product meets all limitations of those claims.

48. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claims of the ’571 patent or the ’912 patent.

49. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the ’571 patent and the ’912 patent in the Notice Letter, Defendants admit the claims of the ’571 patent and the ’912 patent are valid under 35 U.S.C. §§ 101, 102, and 112, and are enforceable.

50. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 103, or unenforceability of any claims of the ’196 patent.

51. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 103, or unenforceability defenses for the ’196 patent in the Notice Letter, Defendants admit the claims of the ’196 patent are valid under 35 U.S.C. §§ 101, 102, and 103, and are enforceable.

52. On information and belief, Defendants’ statements of the factual and legal bases for its assertions regarding non-infringement and invalidity of the Xifaxan® patents are devoid of an objective good faith basis in either facts or the law. This case is exceptional.

53. An actual, real, immediate, and justiciable controversy exists between Salix and Defendants regarding the infringement, validity, and enforceability of the Xifaxan® patents.

54. Salix is commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement of the '571 Patent)

55. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

56. By submitting the Cipla ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '571 patent, Defendants committed an act of infringement of the '571 patent under 35 U.S.C. § 271(e)(2)(A).

57. The '571 patent claims, *inter alia*, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

58. Defendants manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product prior to the expiration of the '571 patent, including any applicable exclusivities or extensions, would infringe one or more claims of the '571 patent under 35 U.S.C. § 271(b) either literally or under the doctrine of equivalents.

59. On information and belief, Cipla's ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of IBS-D in patients, which uses would constitute direct infringement of one or more claims of the '571 patent.

60. On information and belief, these directly infringing uses would occur with Defendants' specific intent and encouragement and would be uses that Defendants know or should know will occur.

61. On information and belief, Defendants' induced infringement of the '571 patent would be willful, intentional, deliberate, and in conscious disregard of Salix's rights under the patent.

62. On information and belief, Defendants would actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses would contravene Salix's rights under the '571 patent.

63. On information and belief, Defendants know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product prior to the '571 patent's expiry would induce the direct infringement of one or more claims of the '571 patent.

64. On information and belief, Defendants' acts would be performed with knowledge of the '571 patent and with intent to encourage infringement prior to the '571 patent's expiry.

65. Defendants were aware of the '571 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '571 patent in the Notice Letter.

66. Salix would be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

COUNT II
(Infringement of the '912 Patent)

67. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

68. By submitting the Cipla ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '912 patent, Defendants committed an act of infringement of the '912 patent under 35 U.S.C. § 271(e)(2)(A).

69. The '912 patent claims, *inter alia*, methods of treating irritable bowel syndrome with rifaximin.

70. Defendants manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product prior to the expiration of the '912 patent, including any applicable exclusivities or extensions, would infringe one or more claims of the '912 patent under 35 U.S.C. § 271(b) either literally or under the doctrine of equivalents.

71. On information and belief, Cipla's ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses would constitute direct infringement of one or more claims of the '912 patent.

72. On information and belief, these directly infringing uses would occur with Defendants' specific intent and encouragement and would be uses that Defendants know or should know will occur.

73. On information and belief, Defendants' induced infringement of the '912 patent would be willful, intentional, deliberate, and in conscious disregard of Salix's rights under the patent.

74. On information and belief, Defendants will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses would contravene Salix's rights under the '912 patent.

75. On information and belief, Defendants know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the '912 patent's expiry will induce the direct infringement of one or more claims of the '912 patent.

76. On information and belief, Defendants' acts would be performed with knowledge of the '912 patent and with intent to encourage infringement prior to the '912 patent's expiry.

77. Defendants were aware of the existence of the '912 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '912 patent in the Notice Letter.

78. Salix would be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

COUNT III
(Infringement of the '196 Patent)

79. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

80. By submitting the Cipla ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '196 patent, Defendants committed an act of infringement of the '196 patent under 35 U.S.C. § 271(e)(2)(A).

81. The '196 patent claims, *inter alia*, a composition comprising a polymorphic form of rifaximin and methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

82. On information and belief, Defendants manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product prior to the expiration of the '196 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(a)-(b) either literally or under the doctrine of equivalents.

83. On information and belief, Cipla's ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses would constitute direct infringement of one or more claims of the '196 patent.

84. On information and belief, these directly infringing uses would occur with Defendants' specific intent and encouragement and would be uses that Defendants know or should know will occur.

85. On information and belief, Defendants would actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses would contravene Salix's rights under the '196 patent.

86. On information and belief, Defendants' direct infringement of the '196 patent would be willful, intentional, deliberate and in conscious disregard of Salix's rights under the patent.

87. On information and belief, Defendants know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the '196 patent's expiry would induce the direct infringement of one or more claims of the '196 patent.

88. On information and belief, Defendants' acts would be performed with knowledge of the '196 patent and with intent to encourage infringement prior to the '196 patent's expiry.

89. Defendants were aware of the '196 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '196 patent in the Notice Letter.

90. Salix would be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Salix requests the following relief:

i. A judgment that the patents-in-suit have been infringed under 35 U.S.C. § 271(e)(2) by Defendants' submission of the Cipla ANDA to the FDA;

ii. A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of the ANDA Product, or any other drug product the use of which infringes the patents-in-suit, be not earlier than the expiration dates of said patents, inclusive of any extension or additional period of exclusivity pursuant to 35 U.S.C. § 271(e)(4)(A);

iii. A preliminary and permanent injunction enjoining Defendants, and all persons acting in concert with Defendants, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product, or any other drug product whose use is covered by the patents-in-suit, prior to the expiration of said patents, inclusive of any extension or additional period of exclusivity;

iv. A judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product, or any other drug product whose use is covered by the patents-in-suit, prior to the expiration of said patents, will infringe and induce infringement of said patents;

v. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Cipla ANDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of any of the patents in suit, inclusive of any extension or additional period of exclusivity;

vi. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

vii. Costs and expenses in this action; and

viii. Such further and other relief as this Court may deem just and proper.

Dated: November 1, 2024

Respectfully submitted,

By: *s/ Harvey Bartle IV*

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